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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,095	08/28/2001	James E. Dahlberg	FORS-06614	8252

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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,095	DAHLBERG ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *109-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109 and 111-122* is/are rejected.

7)☒ Claim(s) *110 and 123* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group II, claims 109-123, in the reply filed on 25 May 2006 is acknowledged.

Priority for the instant claims is granted to the filing date of 08/520,946, which is 30 August 1995. There is insufficient support for the claimed invention earlier in the claimed priority chain.

Claims 110 and 123 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 109, 111-115, 117 and 118 are rejected under 35 U.S.C. 102(e) as being anticipated by Carrino et al. (A, newly cited).

Instant claim 109 is drawn to a kit comprising a cleavage means and an oligonucleotide comprising a duplex, i.e., double-stranded region and a 3' region of one strand which is single-stranded. Claims 111-115 specify that the cleavage means is an enzyme, more narrowly a DNA polymerase, still more narrowly a thermostable one, still more narrowly derived from genus Thermus, and finally comprising a 5' nuclease activity. Claims 117 and 118 specify that the oligonucleotide is less than 100 or 50 nucleotides long, respectively.

Carrino et al. teaches, e.g., at Example 8, bridging columns 25 and 26, oligonucleotides comprising a single-stranded region extending 3' beyond the double-stranded region used in conjunction with Taq polymerase, which is a thermally stable DNA polymerase from genus Thermus having a 5' nuclease activity. As is apparent from the small table within Example 8, the oligonucleotides are less than 50 nucleotides long. There is no definition of a "kit" in the instant specification that would exclude a collection of articles to be used together.

Claims 109, 111 and 117-122 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (B, newly cited).

Claims 109, 111, 117 and 118 were described above. Claim 119 specifies that there is included a second oligonucleotide, more narrowly claimed in claims 120 and 121 as being complementary to the first oligonucleotide 3' single-stranded region. Claim 122 further specifies the presence of a third oligonucleotide.

At column 28, lines 22-57, an oligonucleotide comprising a type II restriction endonuclease site and a 3' single-stranded overhang is taught, in conjunction with a method that also uses a type II restriction endonuclease (line 52) along with a second and third oligonucleotide (linkers at each end). There is no definition of a "kit" in the instant specification that would exclude a collection of articles to be used together.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 116 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim relies upon a thermostable 5' nuclease derived from a thermostable DNA polymerase, which is described in the art, but which also has been modified to have reduced synthetic activity, which is not described fully I either the art or the instant specification.

To eliminate or reduce one function of a multifunction enzyme, those regions of the enzyme giving rise to that function must be altered without affecting the other activity of the enzyme. However, there was no theory or algorithm in the art which would have permitted one of skill in the art to have predicted the folding and therefore activities of proteins generally. Changing one even amino acid in a protein might cause its folded structure to vary in a way that deactivates it, including activities which one wanted to preserve. Set against the backdrop of the art, with its incomplete understanding of folding, such a process would have been unpredictable, and therefore a mere description of the function of such an enzyme would not have led one of skill to know which structures would have been thus described. The specification does not provide information for all such changes to the structure of all such enzymes. As such, one of skill in the art would not have recognized that Applicants were in possession of the full scope of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
31 July 2006

JAMES KETTER
PRIMARY EXAMINER